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Revision Number:	Revision Date:				
Number of Cases Audited:	Principal Investigator:			Number of Protocols Reviewed:	cols Reviewed:
Co-Site Auditor Information					
Name	Title		Affiliation		
Audit Outcome Summary					
Component		Assessment			
IRB and Informed Consent Content Assessment	ssment	-	- construction and cons		
Accountability of Investigational Agents and Pharmacy Operations Assessment	and Pharmacy Operations Assessment				,
Review of Patient Case Records Assessment	ent .				

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Finding

Comments

# I. IRB and Informed Consent Content Review:

A. IRB Review

1. Were each of the selected protocols and informed consents available at the site?

2. Was the most up-to-date version of the protocol and informed consent available?

- 3. Did the auditors review IRB documentation at the site or off-site?
- 4. Were the protocols reviewed for initial IRB approval?
- 5. Were all annual re-approvals reviewed by the IRB in a timely manner?
- 6. Were all amendments reviewed and approved by the IRB?
- 7. Did the auditors follow CTMB guidelines?
- 8. Did the auditors conduct an adequate IRB review?
- B. Informed Consent Content (ICC) Review:
- 1. Were locally used informed consents reviewed?
- 2. Were local informed consent documents reviewed onsite or offsite?

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consent content review? 3. Did the auditors conduct an adequate informed

C. IRB and Informed Consent Content Assessment:

## II. Accountability of Investigational Agents and Pharmacy Operations Review: Finding

Comments

1. Were INDs and for NCI supplied agents used at this site during the time period covered by this audit?

- 2. Was the pharmacy visited?
- 3. Are NCI DARFs in routine use?
- 4. Were NCI DARFs reviewed on-site or off-site?
- 5. Was the pharmacy inspected according to CTMB guidelines?
- 6. Was there adequate security?
- 7. Were satellite NCI DARFs reviewed?
- 8. Did the auditors conduct an adequate Pharmacy/DARF review?

Accountability of Investigational Agents and Pharmacy Operations Assessment:

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Finding

Comments

3. Was each audited case reviewed for eligibility?.

2. Were any major informed consent deficiencies noted?

1. Were patient informed consent documents reviewed?

- 4. Were any major eligibility deficiencies noted?
- 5. Were any major treatment deviations noted?
- 6. Were any major response/disease outcome discrepancies noted?
- 7. Were any major toxicity deficiencies noted?
- 8. Were any major data quality deficiencies identified?
- 9. Were the materials available for the audit adequate?

### Co-Site Visit Report

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10. Did the auditors conduct an adequate review in accordance with CTMB guidelines?

Review of Patient Case Records Assessment:

### Exit Interview

- 1. Was the exit interview attended by the PI?:
- 2. Were the preliminary audit findings stated and discussed? :
- 3. Were Group recommendations made? If "Yes", explain below.:
- 4. Did the auditors conduct an adequate exit interview?:

**Exit Interview Comments:** 

Co-Site Visit Report

Institution Code:

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General Comments:

1. Was the audit conducted according to CTMB Guidelines?:

Overall Comments and Recommendations:

Prepared By Date Approved By Date